

Amendment and Response under 37 C.F.R. 1.116

Applicant: Winthrop D. Childers

Serial No.: 09/878,108

Filed: June 7, 2001

Docket No.: 10008114-1 (H301.392.101)

Title: RAPID PHARMACEUTICAL COMPONENT SCREENING DEVICES AND METHODS

IN THE CLAIMS

Please cancel claims 2, 27, 29-30, and 35.

Please amend claims 1, 28, 36, 37, 40, 41, and 43 as follows:

1. (Currently Amended) An automated method for analyzing substances containing cellular material, the method comprising:

removably receiving at least one consumable cartridge containing at least one potential pharmaceutically active agent into a test apparatus, the test apparatus comprising at least one liquid ejection device including the at least one consumable cartridge and an electronically actuated drop-on-demand printhead acting in fluid communication and electronic communication with the at least one consumable cartridge;

activating the test apparatus having at least one liquid ejection device acting in cooperation with an electronically actuated printhead to dispense a first defined volume of the at least one potential pharmaceutically active agent from the drop-on-demand printhead of the at least one liquid ejection device, the volume containing at least one potential pharmaceutically active agent, the first defined volume dispensed into contact with at least one defined volume of a substance containing a target cellular material wherein the target cellular material is at least one of whole cells and or recognized cellular components from intact cells;

capturing and maintaining information, via a memory storage device of the at least one consumable cartridge, pertaining to at least one of a function of the at least one consumable cartridge and the at least one potential pharmaceutically active agent;

detecting in the at least one defined volume of the substance a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent;

generating information indicative of the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material; and

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analyzing the generated information to generate a correlation factor regarding the pharmacological effect of the relative effectiveness of the at least one potential pharmaceutically active agent on the target cellular material.

2. (Cancelled)

3. (Previously Presented) The automated method of claim 1, further comprising:

positioning the at least one defined volume of containing the target cellular material on a suitable testing substrate, the positioning step occurring prior to the activation of the test apparatus,

wherein the at least one defined volume of the substance containing the target cellular material is maintained in contact with the suitable testing substrate, the suitable testing substrate having a contact surface which is reactively inert to interaction with the target cellular material under study.

4.(Previously Presented) The automated method of claim 3 wherein the at least one defined volume of the substance containing the target cellular material comprises a plurality of individual volumes, wherein each individual volume is between about 1 and about 500 picoliters and wherein characteristics of the substance containing the target cellular material may vary from individual volume to individual volume.

5.(Previously Presented) The automated method of claim 4 wherein the at least one liquid ejection device dispenses varying quantities of the at least one potential pharmaceutically active agent to contact the individual volume of the substance containing the target cellular material.

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6.(Previously Presented) The automated method of claim 4 wherein the at least one liquid ejection device dispenses a quantity of the at least one potential pharmaceutically active agent into contact with selected individual volumes present, the dispensed quantity varying compositionally across the individual volumes of the substance containing the target cellular material.

7.(Previously Presented) The automated method of claim 4 wherein the plurality of individual samples are arranged on the suitable testing surface in an array capable of yielding statistically viable data.

8.(Original) The automated method of claim 7 wherein the individual samples are arranged in a defined two-dimensional array.

9.(Original) The automated method of claim 7 wherein the individual samples are arranged in an interactive linear array.

10.(Previously Presented) The automated method of claim 1 further comprising the step of interactively activating at least one second liquid ejection device in cooperation with an electrically actuated printhead to dispense a second defined volume of a potential pharmaceutically active substance into contact with the at least one defined volume of the substance containing cellular material.

11. – 27.(Cancelled)

28. (Currently Amended) The automated method of claim ~~27~~1 wherein the consumable cartridge ~~removably associated with the at least one liquid ejection device~~ further comprises control electronics configured to convert received information into control output pertinent to analyzing the generated information.

29.(Cancelled)

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30.(Cancelled)

31.(Previously Presented) The automated method of claim 1 further comprising:
upon generation of the correlation factor, altering dispensation of the potential
pharmaceutically active material in an iterative manner in subsequent volumes of a substance
containing cellular material.

32.(Previously Presented) The method of claim 31 wherein the iterative alteration is a
function of ongoing factorial analysis.

33.(Previously Presented) The method of claim 32 wherein each of the plurality of
volumes are a range between about 1 picoliter and 500 picoliters.

34.(Previously Presented) The method of claim 33 wherein the first volume is present as a
plurality of volumes arranged in a two dimensional array.

35.(Cancelled)

36.(Currently Amended) An automated method for analyzing substances containing
cellular material, the method comprising:

removably receiving into a test apparatus ~~activating a test apparatus having~~ at least
one liquid ejection device, ~~including~~ comprising at least one consumable cartridge
~~removably associated with the at least one liquid ejection device and~~ consumable cartridge
including at least one ~~interior~~ chamber ~~defining a fixed volume~~ containing at least one
potential pharmaceutically active agent, a memory storage device, and ~~acting in cooperation~~
~~with an electronically actuated~~ drop-on-demand printhead in fluid communication with the
chamber;

activating the test apparatus to dispense via the printhead a first defined volume
containing the at least one potential pharmaceutically active agent from the at least one liquid
ejection device, ~~the first defined volume dispensed~~ into contact with at least one defined

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volume of a substance containing a target cellular material wherein the cellular material is at ~~least one of whole cells or~~ and recognized cellular components from intact cells;

capturing and maintaining, via the memory storage device of the cartridge,
information pertaining to at least one of a function of the cartridge and the at least one
potential pharmaceutically active agent contained within the cartridge;

detecting in the at least one defined volume a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent;

generating information indicative of the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material; and

analyzing the generated information to generate a correlation factor regarding the
pharmacologic effect of the relative effectiveness of the at least one potential pharmaceutically active agent on the target cellular material.

37. (Currently Amended) The method of claim 36 2 wherein activating the test apparatus comprises:

providing at least one memory storage device in the cartridge that is capable of capturing and maintaining information pertaining to at least one of a function of the cartridge and the at least one potential pharmaceutically active agent contained within the at least one chamber of the cartridge.

38. (Previously Presented) The automated method of claim 37 wherein activating the test apparatus comprises:

providing control electronics in the cartridge configured to convert the generated information as part of analyzing the generated information.

39. (Currently Amended) The automated method of claim 36 2 wherein activating the test apparatus comprises:

removably associating the cartridge relative to the printhead.

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- ~ 40.(Currently Amended) The automated method of claim 36 wherein activating the test apparatus comprises:

integrally connecting ~~associating~~ the chamber cartridge to the printhead as a single, monolithic structure.

- 41.(Currently Amended) An automated method for analyzing substances containing cellular material, the method comprising:

removably receiving at least one replaceable cartridge containing at least one potential pharmaceutically active agent into a test apparatus, the test apparatus comprising at least one liquid ejection device including the at least one replaceable cartridge and an electronically actuated drop-on-demand printhead acting in fluid communication and electronic communication with the at least one replaceable cartridge;

~~activating a the test apparatus having at least one liquid ejection device acting in cooperation with an electronically actuated printhead to dispense a first defined volume containing the at least one potential pharmaceutically active agent from the drop-on-demand printhead of the at least one liquid ejection device, the first defined volume dispensed into contact with at least one defined volume of a substance containing a target cellular material wherein the target cellular material is whole cells or recognized cellular components from intact cells;~~

detecting in the at least one defined volume a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent;

generating a first information indicative of the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material; and

dispensing interactively, based upon the generated information, a second defined volume of at least one potential pharmaceutically active agent from the at least one liquid ejection device into contact with the at least one defined volume of the substance containing the target cellular material; and

generating a second information indicative of the effect of the second defined volume of at least one potentially pharmaceutically active agent on the target cellular material.

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42. (Previously Presented) The method of claim 41 wherein dispensing the second defined volume comprises selecting the at least one potential pharmaceutically active agent of the second defined volume to differ from the at least one potential pharmaceutically active agent of the first defined volume by at least one of a type, concentration, and a quantity of the respective at least one potential pharmaceutically active agents of the first and second defined volumes.

43. (Currently Amended) The method of claim 42 wherein dispensing the first defined volume and dispensing the second defined volume comprises:

dispensing the first defined volume from a first chamber within the at least one replaceable cartridge and the second defined volume from a second chamber within the at least one replaceable cartridge separate from the first chamber.